FILED
Court of Appeals
Division II
State of Washington
2/6/2023 4:34 PM
No. 57403-9-II

COURT OF APPEALS, DIVISION II, OF THE STATE OF WASHINGTON

RCCH TRIOS HEALTH, LLC, a Delaware Limited Liability Company,

Appellant,

v.

DEPARTMENT OF HEALTH OF THE STATE OF WASHINGTON and KADLEC REGIONAL MEDICAL CENTER,

Respondents.

APPELLANT'S OPENING BRIEF

Donald W. Black, WSBA #25272 Paul J. Dayton, WSBA #12619 Madeleine C. Haller, WSBA #53341 Attorneys for RCCH Trios Health, LLC OGDEN MURPHY WALLACE, PLLC 901 5th Ave, Suite 3500 Seattle, WA 98164 Tel: 206-447-7000/Fax: 206-447-0215

TABLE OF CONTENTS

		Page
I.	INTRODUC	CTION 1
II.	ASSIGNMI	ENTS OF ERROR4
III.	STATEME	NT OF THE CASE6
	a.	Trios operates a hospital in southeastern
		Washington with an established cardiac care
		program 6
	b.	CN requirements are intended to assure the
		health of citizens in the state and include
		proof of need for new PCI providers based
		on a methodology described in WAC 246-
		310-745
	c.	Trios applied for a CN and provided
		evidence of need
	d.	DRGs are used to define PCIs and generally
		for hospital billing
	e.	The Program refused to consider the omitted
		PCIs and denied Trios' application 16
	f.	The Program's errors were compounded in
		the administrative review process
IV.	STANDAR	D OF REVIEW 19
V.	ARGUMEN	NT
	a.	The Department erroneously concluded that
		the 31 additional PCIs identified by Trios
		must be excluded from the Department's
		need assessment
	b.	The Department erroneously concluded that
		the Department lacks discretion to look
		outside three sources when counting PCIs to
		determine need
VI.	CONCLUS	ION34

TABLE OF AUTHORITIES

Page
Cases
Associated Press v. Washington State Legislature, 194 Wn.2d
915, 454 P.3d 93 (2019)31
City of Edmonds v. Bass, 16 Wn. App. 2d 488, 481 P.3d 596
(2021)31
Cobra Roofing Service, Inc. v. Dep't of Labor & Industries, 122
Wn. App. 402, 97 P.3d 17 (2004)21
Dep't of Ecology v. Campbell & Gwinn, LLC, 146 Wn.3d 1, 43
P.3d 4 (2002)
King County Pub. Hosp. Dist. No. 2 v. Washington State Dep't
of Health, 178 Wn.2d 363, 309 P.3d 416 (2013)20
Overlake Hosp. Ass'n v. Dep't of Health of State of
Washington, 170 Wn.2d 43, 239 P.3d 1095 (2010) 23, 24
Providence Health & Services – Washington v. Dep't of Health
of the State of Washington, 194 Wn. App. 849, 378 P.3d 249
(2016)
(1984)
195 (1984)
State v. S.G., 11 Wn. App. 2d 74, 451 P.3d 726, 728 (2019) 31
State, Dep't. of Revenue v. Bi-Mor, Inc., 171 Wn. App. 197,
286 P.3d 417 (2012)
Statutes PGW 24 05 570
RCW 34.05.570
RCW 70.38.128
Regulations
RCW 70.38.015
WAC 246-10-701

WAC 246-310-010	
WAC 246-310-200	
WAC 246-310-210	
WAC 246-310-220	
WAC 246-310-610	
WAC 246-310-700	
WAC 246-310-705	
WAC 246-310-720	
WAC 246-310-745	passim

I. <u>INTRODUCTION</u>

Appellant RCCH Trios Health, LLC (Trios), operates Trios Southridge Hospital, an acute care hospital in Kennewick, Washington. The hospital provides interventional cardiology services known as percutaneous coronary interventions (PCIs) in emergent circumstances using cardiac catheterization labs. Believing that its community had unmet need for *elective* PCIs (procedures required for patients whose cardiac function is stable), in 2019, Trios applied to the Department of Health for the certificate of need (CN) required by Washington law in order to provide such services. RCW 70.38.128; WAC 246-310-700. The Department concluded that threshold need requirements were not met and denied Trios' application. By the Department's calculation, unmet PCI volume was 188 in Trios' service area, below the minimum of 200 that warrants a CN. WAC 246-310-720.

The Department erred in denying Trios' request for a CN. The Department failed to adhere to the need forecasting methodology in WAC 246-310-745, which required the Department to include, in its calculation of unmet PCI volume, all PCIs as "defined by diagnosis related groups (DRGs) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest." WAC 246-310-745(4). The Department conceded below that Trios identified additional PCIs meeting the relevant DRG definitions but not included in the Department's calculation. The Department refused to include the additional PCIs because in those instances, the patient's care was coded for hospital billing purposes based on treatment other than the PCI.

The Department did not offer a construction of WAC 246-310-745(4) supporting its position that the additional PCIs need not be included, and there is none. Nor did the Department

explain how such an approach of counting less than all qualifying PCIs fits with the legislative direction that the intent of the CN process is to, "promote, maintain and assure the health of all citizens of the state..." and "provide accessible health services, health manpower, [and] health facilities." RCW 70.38.015(1).

When WAC 246-310-745 is correctly applied, qualifying PCIs exceeded the need threshold, so the Department's denial of a CN to Trios was error and must now be reversed.

The Department also erroneously excluded from its need assessment PCIs performed in neighboring states on residents of Trios' service area, as well as PCIs performed at a hospital within the service area that later closed. Below, the Department originally took the position that it had discretion to consider the additional PCIs but was not required to do so because the data was allegedly not available to other potential applicants (there were none). The Department later claimed that it lacked discretion to consider the data because it did not originate from

one of three sources listed in a rule providing that data sources for PCI volumes "include" the three sources. WAC 246-310-745(7). Neither position is supported by the applicable regulations. The Department's final order adopts the erroneous view that the Department lacked discretion to consider the PCIs. The denial of a CN to Trios must be reversed on this ground as well.

II. ASSIGNMENTS OF ERROR

- A. The Department erred by failing to correctly apply CN criteria including WAC 246-310-745 in determining need for additional PCI services, and consequently rejecting Trios' application for a CN based on Trios' alleged failure to demonstrate need.
- B. The Department erred in its assessment of need by failing to consider certain PCIs meeting the definitions of DRGs that describe catheter-based interventions, as required by WAC 246-310-745(4). Specifically, the Department erred by

concluding that PCIs that were part of other hospital care provided to the patient, and were coded with a DRG based on such other care, are not counted in the PCI need methodology in WAC 246-310-745. Issues relevant to the foregoing two errors (A and B) include:

- Whether the rule describing PCIs by reference to DRG
 definitions may be construed to require that hospital care
 must be coded with those DRGs in order to be included in
 the PCI need assessment, when such coding may be
 assigned based on unrelated conditions or care.
- but not coded with those DRGs must be included in the Department's assessment of need, in order to give effect to the plain text of WAC 246-310-745(4) and the Department's statutory obligation to assure adequate health services and the health of all residents of the state.

- C. The Department erred by concluding that data sources for PCI case volumes can only be certain sources named in WAC 246-310-745(7) and (9). Issues relevant to this error include:
 - Whether use of the word "include" in WAC 246-310-745(7) introduces an exhaustive list of data sources.
 - Whether the Department has discretion to look outside
 three data sources when necessary to accurately forecast
 need for health services, consistent with the purpose of the
 CN process to assure adequate health services and the
 Department's past practice of relying on other sources to
 identify Washington patients leaving the state for services.

III. STATEMENT OF THE CASE

a. Trios operates a hospital in southeastern Washington with an established cardiac care program.

Trios Southridge Hospital is an acute care hospital in Kennewick, Washington (referred to as Trios or the "hospital"

herein). Administrative Record (AR) 603. The hospital has two cardiac catheterization labs where a variety of diagnostic and therapeutic services are performed by contracted interventional cardiologists. AR 604-605; *see also* AR 620-621.

PCIs are invasive but nonsurgical procedures performed by cardiologists to revascularize (restore blood flow) within obstructed arteries of the heart. WAC 246-310-705(4). PCIs are currently performed Trios only in emergent at circumstances. AR 87; see also WAC 246-310-705(3) (defining emergent PCIs as those required immediately in the treating physician's judgment). Trios does not have Department approval to provide "elective PCIs" that are performed on patients whose cardiac function is stable before the procedure, as defined by the Department. WAC 246-310-705(2). Thus "elective" does not mean the PCI is not medically necessary. When an elective PCI is appropriate for a Trios patient, the patient must be transferred to a different facility, resulting in transport costs and delays in treatment. AR 612, 631.

b. CN requirements are intended to assure the health of citizens in the state and include proof of need for new PCI providers based on a methodology described in WAC 246-310-745.

A CN is written authorization issued by the Department's CN Program (the "Program")¹ to implement a proposal for a particular undertaking. WAC 246-310-010(11). The Program is a part of a statutory framework intended to "assure the health of all citizens of the state" and "provide accessible health services, health manpower, [and] health facilities." RCW 70.38.015(1). CNs are required for certain healthcare facilities and services, including elective PCIs at hospitals that do not perform on-site cardiac surgery. RCW 70.38.128. The CN rules, Ch. 246-310 WAC, set forth general standards for issuance of a CN (see WAC)

¹ The Program is a division of the Department. We use "Program" herein to refer to actions taken specifically by the Program and "Department" to refer to the final agency action, including action taken or positions adopted by the Program and affirmed during the administrative review process.

246-310-200), as well as requirements specific to PCIs. *See generally* WAC 246-310-700 to WAC 246-310-755. The criteria for approval include whether there is need for elective PCI services in the applicant's region, described as their "planning area" by the CN rules. WAC 246-310-210(1); WAC 246-310-705(5). Other criteria include financial feasibility, structure and process of care, and cost containment. WAC 246-310-200(b)-(d); *see also* WAC 246-310-220, 230, and 240. Only need is at issue in this appeal.

The CN rules contain a five-step methodology to forecast need for elective PCI services (referred to as the "methodology" herein). WAC 246-310-745(10). The first step requires computation of a planning area's historical "use rate" by dividing the "total number of PCIs" performed in a certain time period by a segment of the population. WAC 246-310-745(10), Step 1. PCIs may be inpatient or outpatient procedures and the use rate must include both. *Id*. The use rate is applied in later steps of the

methodology to project future need. WAC 246-310-745(10), Steps 2-5. The methodology must demonstrate numeric need of at least 200 before a CN may issue. WAC 246-310-745(10), Steps 4 and 5; *see also* WAC 246-310-720. Undercounting the total number of PCIs in Step 1 results in a use rate that is too low and ultimately causes underestimation of need, preventing approval of a CN. The Department agrees that the purpose of the methodology is to identify whether there are "shortfalls in PCI availability." AR 232-233 (deposition testimony of Program analyst Elizabeth Harlow).

c. Trios applied for a CN and provided evidence of need.

Trios is located in Planning Area 2, consisting of Benton, Columbia, Franklin, Garfield, and Walla Walla counties. AR 603; WAC 246-310-705(5). The Benton/Franklin area, including Kennewick, has a rapidly growing population, and more than 80 percent of all PCIs in 2017 were performed on residents of one of these two counties. AR 611. Kadlec Regional Medical Center

(Kadlec), a respondent in this proceeding, is the only hospital with a CN to provide elective PCIs in Planning Area 2. AR 603.

In January 2019, Trios submitted a letter of intent to the Program indicating its intent to apply for a CN for elective PCI services. AR 595. In February 2019, shortly before the application deadline, the Program posted online its calculation of need for new PCI providers in Washington. See AR 876. The Program is not required to do this, nor do applicable regulations state that the Program's posted calculation is the authoritative or final determination of need for an application cycle. The Program ran the methodology twice using two different data sets: 1) data from the Comprehensive Abstract Reporting System (CHARS) on inpatient PCIs, combined with survey responses from hospitals regarding the number of outpatient PCIs performed; and 2) data from the Clinical Outcomes Assessment Program (COAP). AR 29. The first data set identified greater numeric need in Planning Area 2. Using this data set, the Program

calculated numeric need of 182, below the minimum of 200 required for issuance of a CN. AR 610.

After review of the Program's calculations, Trios identified a need for additional PCI services in Planning Area 2 and submitted an application for a CN. AR 596-656. Trios was the only hospital from Planning Area 2 to do so in 2019. AR 89. Accordingly, the Program converted its review of Trios' application from "concurrent" to "regular" review under the CN rules. AR 89.

During the application review process, Trios provided data to the Program that was not incorporated in the Program's February calculation of need but was necessary for accurate forecasting of need in Planning Area 2. Trios identified 31 PCIs provided to hospital inpatients in 2017, the year from which data was used for the Program's need projection. AR 848-851. These additional PCIs met the definition of PCIs for purposes of the methodology: "cases as defined by diagnosis related groups

(DRGs) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest" (excluding interventions performed on persons 14 or younger). WAC 246-310-745(4). The Program does not contend otherwise, and yet it refused to alter its need calculation or even consider the data, as further explained below. AR 251 (deposition testimony of Program analyst Elizabeth Harlow, who evaluated Trios' application, that she did not consider the 31 PCIs because she was relying on the Program's calculation of need).

d. DRGs are used to define PCIs and generally for hospital billing.

DRG codes are generally used to define services for the purpose of hospital billing. Each DRG code corresponds to a definition in a manual published by CMS. AR 345; *see also* AR 353-358 (excerpt from CMS manual). The DRGs associated with PCIs are DRGs 246 through 251, each of which defines a type of

PCI. See AR 353-358 (excerpt from CMS manual); see also AR 291 (deposition testimony of Program analyst Randall Huyck that DRGs 246-251 are used by the Program to identify PCIs). For example, DRG 246 is a "Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents." AR 353.

Only one DRG is assigned per hospital admission based on the patient's principal diagnosis and other factors. AR 344. Each procedure is also separately coded using the ICD-10 system. See AR 344-345. If a patient receives multiple procedures during the same hospital stay, a DRG code is not assigned for all procedures. AR 344; see also AR 850. DRGs 246–251 are typically assigned to patients who receive a PCI unless a different DRG is more appropriate based on factors related to the patient's hospital stay. AR 344; see also AR 850 ("the patient could have been admitted for an unrelated issue, and then began displaying symptoms such as chest pain and elevated

cardiac enzyme values that resulted in a cardiology consultation and determination that a coronary intervention was necessary" or "the patient could also have had co-morbidities or another diagnosis that resulted in them being assigned to a higher-weighted DRG."). This means that whether a patient who received a PCI is assigned a corresponding DRG code depends on the timing of the PCI in relation to other procedures performed, the cause of admission, and other factors.

The 31 PCIs identified by Trios met one or more of the definitions in DRGs 246 through 251, but were coded with a different DRG based on other factors related to each patient's hospital stay and not the PCI itself. Trios located the 31 PCIs within CHARS. AR 849 ("The PCIs performed outside of DRGs 246-251 performed on Planning Are residents are clearly visible in the six procedure code columns included in CHARS."). Nothing prevented other hospitals or the Department from obtaining or reviewing the same data. *See* AR 288 (Huyck

deposition testimony that procedure codes are visible within CHARS).

As part of proving need, and in addition to the 31 PCIs described above, Trios also provided evidence to the Program of PCIs performed on residents of Planning Area 2 in Oregon and Idaho, as well as PCIs performed at a hospital in Planning Area 2, Walla Walla General, that had recently closed and had failed to report data to the Department regarding PCI services in its final year of operation. AR at 610, 669-670, 696-707, 734-736, 846-848. Trios demonstrated that when the PCIs described above (collectively, including the 31 PCIs, the "omitted PCIs") were included in an assessment of need, need in Planning Area 2 was established. AR 851.

e. The Program refused to consider the omitted PCIs and denied Trios' application.

The Program eventually incorporated some data regarding PCIs performed in Oregon into a revised calculation of need, which increased projected net need to 188. AR 17, 75.

Otherwise, the Program did not take steps to analyze the omitted PCIs or incorporate them into its need assessment in any manner.

In regard to the 31 PCIs not coded with DRGs 246-251, the Program's refusal to consider the data was not based on a disagreement over whether the PCIs met the relevant DRG definitions. The Program's analyst who reviewed Trios' application testified that she did not consider the additional 31 PCIs because she believed (incorrectly) that the data was not publicly available, and she did not know if the PCIs met the relevant definitions. AR 251-254. Trios obtained evidence of the 31 PCIs from the same CHARS database used by the Program. AR 849.

The Program denied Trios' application in a written evaluation issued in February 2020. AR 9-71. The Program erroneously concluded that there was insufficient need for a new PCI provider in Planning Area 2 and therefore, WAC 246-310-210(1) was not satisfied. AR 34. Based solely on this conclusion,

the Program concluded that Trios' application also did not satisfy other CN criteria. AR 51, 59, and 70-71 (finding certain requirements under WAC 246-310-220, 230, and 240 not satisfied based on the application's alleged failure to satisfy WAC 246-310-210); *see also* AR 914-918 (analysis by the Program that Trios would meet various criteria "contingent upon a demonstration of need").

f. The Program's errors were compounded in the administrative review process.

Applicants who are denied a CN have the right to an adjudicative proceeding before the Department's Adjudicative Service Unit. WAC 246-310-610(1). Trios timely initiated such a proceeding. AR 2-7. The parties to the proceeding were Trios, the Program, and Kadlec as a permitted intervenor. AR 172-174. Before the scheduled hearing, Kadlec moved for summary judgment against Trios, arguing that the Department was barred

from considering the omitted PCIs on grounds described below. AR 180-195. The Program joined in Kadlec's motion on the basis that its calculation of need did not justify a new provider of elective PCIs in Planning Area 2. AR 317. A Health Law Judge granted Kadlec's motion in Findings of Fact, Conclusions of Law, and Initial Order on Summary Judgment (the "Initial Order"). AR 529-544. On further administrative review requested by Trios under WAC 246-10-701(1), the Initial Order was affirmed by a Final Order on Summary Judgment and Cross-Motion for Summary Judgment dated October 22, 2021 (the "Final Order"). AR 582-589. The Final Order was affirmed in Thurston County Superior Court by order dated September 7, 2022. Clerk's Papers at 24. Trios timely filed this appeal.

IV. STANDARD OF REVIEW

This case is brought under the Administrative Procedure Act (APA), Ch. 34.05 RCW. The Court of Appeals applies the APA standards directly to the record before the agency, in this

case the Department of Health. Providence Health & Serv. -Washington v. Dep't of Health of the State of Washington, 194 Wn. 849, 856. 378 P.3d 249 (2016). RCW App. 34.05.570(3) provides several grounds for which a reviewing court may reverse an administrative order. These include when the agency erroneously interpreted or applied the law or failed to follow a prescribed procedure. RCW 34.05.570(3)(c), (d). Relief from an agency order is also required when the order exceeds the agency's authority, is inconsistent with a rule of the agency, is not supported by substantial evidence, or is arbitrary and capricious. RCW 34.05.570(3)(b), (e), (h), (i). "Arbitrary and capricious" means that the agency's decision is the result of willful and unreasoning disregard of the facts and circumstances. King County Pub. Hosp. Dist. No. 2 v. Washington State Dep't of Health, 178 Wn.2d 363, 372, 309 P.3d 416 (2013).

The party challenging agency action, in this case Trios, has the burden of proof, but this Court must make a de novo

judgment whether the Department adhered to the methodology in WAC 246-310-745. Cobra Roofing Serv., Inc. v. Dep't of Labor & Indus., 122 Wn. App. 402, 409, 97 P.3d 17 (2004). The Court may defer to the Department's construction of its regulations only if it conforms to legislative intent. Id. at 409; Safeco Ins. Companies v. Meyering, 102 Wn.2d 385, 390-391, 687 P.2d 195 (1984) (under the "error of law" standard, the reviewing court conducts a de novo review independent of the agency's actions). Deference to the agency's construction of a rule does not extend to the Department's administrative choices, such as a construction that favors labor-saving practices.

If, as in this case, the administrative decision was issued on summary judgment, a reviewing court overlays the error of law standard with the summary judgment standard, and reviews an agency's interpretation or application of the law de novo while viewing the facts in the light most favorable to the nonmoving

party. State, Dep't. of Revenue v. Bi-Mor, Inc., 171 Wn. App. 197, 202, 286 P.3d 417 (2012).

V. <u>ARGUMENT</u>

a. The Department erroneously concluded that the 31 additional PCIs identified by Trios must be excluded from the Department's need assessment.

This case concerns the Department's refusal to include PCIs meeting the definition in WAC 246-310-745(4) and consequently denying Trios a CN for elective PCIs. Of concern to the public, the Department's decision denied the residents of Planning Area 2 a hospital facility to address unmet need for cardiology care.

Putting the case in concrete terms, if you go to the hospital with chest pain and receive a PCI and your visit is assigned a DRG code on that basis, the Program will count your PCI for its need calculation. If you go to the hospital for a different reason and your care is coded on that basis, and the doctor determines

you also need a PCI, the Program will not count that PCI for need purposes even though the same procedure was performed.

The crux of the parties' dispute is construction of WAC 246-310-745(4), defining PCIs as "cases as defined by" DRGs that "describe catheter-based interventions involving the coronary arteries and great arteries of the chest..." The Department took the position below that "defined by" actually means "coded by," but it did not parse the language of the regulation to justify such a construction, nor can it reconcile such an alteration of the text with the legislative intent that the CN process is to enable full access to health care.

The rules of statutory construction apply to regulatory interpretation. *Overlake Hosp. Ass'n v. Dep't of Health of State of Washington*, 170 Wn.2d 43, 51-52, 239 P.3d 1095 (2010). If the meaning of a rule is plain and unambiguous on its face, a reviewing court will give effect to that plain meaning. *Id.* at 52. A paramount concern is ensuring that the rule is interpreted in a

manner consistent with the underlying policy of the relevant statute. Id.; see also Dep't of Ecology v. Campbell & Gwinn, LLC, 146 Wn.3d 1, 11, 43 P.3d 4 (2002) (the plain meaning of a statute is discerned from all that the legislature has said in the statute and related statutes which disclose legislative intent about the provision in question). Relevant here, the "overriding purpose" of the CN statute is to "promote, maintain, and assure the health of all citizens in the state, [and] provide accessible health services, health manpower, [and] health facilities." RCW 70.38.015(1); Overlake Hosp. Ass'n, 170 Wn.2d at 55. Nothing in this suggests reading WAC 246-310-745(4) to limit the calculation of unmet PCI volume based on hospital coding decisions.

The Final Order adopts the Initial Order's conclusion that, "WAC 246-310-745(4) is clear in requiring that cases be defined by DRG—not procedure codes—when calculating need for new PCI programs." AR 541 (Conclusion 2.17). This misstates and

actually reverses Trios' point. Trios has emphasized that PCIs are defined by the DRGs that describe "catheter-based interventions involving the coronary arteries and great arteries of the chest," but are not limited to PCIs coded with such DRGs. Relevant PCIs may be located by use of procedure codes, but only the definitions in DRGs 246 through 251 determine which PCIs qualify for inclusion in the methodology. It is the Program, not Trios, that seeks to depend on hospital coding and the Final Order's reasoning is better applied to reject that approach. The order erroneously continues, "Consequently, Trios's request to use procedure codes is outside the methodology set forth in the administrative rules and must be rejected." AR 540 (Conclusion 2.17). This is a continuation of the false premise that Trios invokes coding as a basis for applying the regulation and fails for the reasons stated above.

The Department was forced to its "coding" argument because it could not offer a construction of the regulation

supporting its view that it need not consider the 31 PCIs meeting the definitions in DRGs 246-251.² It applied WAC 246-310-745(4) to mean that qualifying PCIs must be coded using the relevant DRGs, but it plainly does not say that, and no rule of construction may be invoked to overcome the rule's plain "Defined by" "coded with" meaning. and interchangeable. The distinct meaning of "define"—to determine or identify the essential qualities or meaning of something, https://www.merriam-webster.com/dictionary/define—must be given effect in the context of WAC 246-310-745. DRGs 246-251 "describe catheter-based interventions involving the coronary arteries and great arteries of the chest," but each of those DRGs also has its own definition. For example, DRG 246 is a "Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents." AR 353. Various

² The Department's failure to offer a construction of the words used means it is not entitled to deference under *Overlake* and similar cases.

procedure codes are associated with each DRG. See AR 353-358. These procedure codes (and the procedures that are coded with them) meet the definition of the DRG they are associated with.

Trios provided undisputed evidence below that all of the 31 cases located in CHARS meet the definition of one or more of DRGs 246-251. This evidence included a table listing each of the 31 PCIs with their procedure codes and the DRGs that could have been assigned based on such procedure codes, had another DRG not taken precedence. *See* AR 345 (explanation of table) and AR 349-351 (table).³ For example, PCIs located by procedure code 027043Z, which appears in several of the 31 cases, and which indicates dilation of one coronary artery with a drug-eluting stent by "percutaneous approach," is encompassed within DRG 246 ("Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents") and DRG

³ The table lists 52 cases, but Trios relied only on the 31 cases that clearly included a PCI. AR 850.

247 ("Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC"). AR 344-345; AR 352-358. All 31 cases thus meet the definition in WAC 246-310-745(4) because they are defined by the relevant DRGs.

If the drafters meant "coded as" instead of "defined by" in WAC 246-310-745(4), they could easily have said so. They did not. Engaging in a de novo review of WAC 246-310-745(4) and viewing the record favorably to Trios, this Court must apply the "defined by" language in identifying those PCIs that must be included in the methodology.

In making this judgment, the Court must also have in mind that the limited reading of WAC 246-310-745(4) adopted in the Final Order has the effect of undercounting PCIs and preventing issuance of a CN when need is established. This result serves no legitimate public interest. It helps only competitors such as Kadlec, which not surprisingly brought the motion for summary judgment that is the basis for this appeal. And, it may serve the

Program's interest in maintaining a more streamlined review whereby it can rely on DRG coding and is not required to make a complete assessment of need. But labor-saving practices is not part of the purpose of the CN process. Having in mind the overriding purpose of the CN statute and the Program to "promote, maintain, and assure the health of all citizens of the state, provide accessible health services, health manpower, health facilities, and other resources...," WAC 246-310-745 must be applied to advance that goal. All PCIs meeting the definitions of DRGs 246-251 must be included.

Trios identified PCIs that met the definitions of DRGs 246-251 but were excluded from the Program's calculation. The Final Order justifies exclusion of the PCIs based on a gloss on WAC 246-310-745(4) that cannot be squared with the language in the rule or the intent of the legislature. The Final Order must be reversed on this ground because it is legally erroneous, is inconsistent with WAC 246-310-745, does not conform to the

procedure required by that rule, and is arbitrary and capricious insofar as it rejects application of the rule to identify the demonstrated need for PCI services in Planning Area 2. RCW 34.05.570(3)(b), (e), (h), (i).

b. The Department erroneously concluded that the Department lacks discretion to look outside three sources when counting PCIs to determine need.

Trios also asked the Program to consider PCIs performed on Planning Area 2 residents in adjacent states and at the now-closed Walla Walla General Hospital. This consisted of (1) data on inpatient and outpatient PCIs performed by Oregon hospitals, acquired from the Oregon Association of Hospitals and Health Systems and Trilliant Health, a data analytics firm; (2) data from Trilliant Health on outpatient PCIs performed at Walla Walla General; and (3) data on inpatient and outpatient PCIs performed at

a hospital in Idaho located just across the Washington/Idaho border.

AR at 610, 669, 694-707, 734-736, 846-848.

The Final Order adopts the Initial Order's conclusion that, "the data sources for PCI case volumes can only be those sources named in WAC 246-310-745(7) and (9)." AR 540 (Conclusion 2.16). WAC 246-310-745(7) states that "data sources for adult elective PCI case volumes <u>include</u>" CHARS, COAP, and survey data collected by the Department regarding outpatient PCIs.

Use of the word "include" introduces examples, not an exhaustive list; it is a word of "enlargement" rather than "limitation." *Associated Press v. Washington State Legislature*, 194 Wn.2d 915, 935, 454 P.3d 93 (2019); *Queets Band of Indians v. State*, 102 Wn.2d 1, 4, 682 P.2d 909 (1984); *City of Edmonds v. Bass*, 16 Wn. App. 2d 488, 499, 481 P.3d 596 (2021); *State v. S.G.*, 11 Wn. App. 2d 74, 78, 451 P.3d 726, 728 (2019).

As used in the context of WAC 246-310-745, which is aimed at capturing PCI case volumes to calculate the "total number of

PCIs" performed on residents of a planning area (WAC 246-310necessarily "include" 745(7) and (10)),allows other sources. Accordingly, the Program has exercised its discretion to consider sources other than those stated in the rule, including in 2019 when it used an Oregon database to identify PCIs performed on Washington residents at Oregon hospitals. AR 243. The Final Order adopts the Initial Order's erroneous conclusion that this data was, "based, at least in part, on information obtained from CHARS." AR 540 (Conclusion 2.16). The Oregon data which the Program incorporated into its need calculation was not based in part, or at all, on information obtained from CHARS. The record is clear that the data was obtained from an Oregon database that is not listed in WAC 246-310-745(7). AR 243 (Harlow testimony that the database, "wasn't actually CHARS").

In concluding that the Program may not look outside the three sources, the Final Order relies on a misreading of a different section, WAC 246-310-745(9). Section 9 limits data "used for

evaluating PCI applications submitted during the concurrent review cycle" to "the most recent year end data" as reported by CHARS, or the "most recent survey data" or COAP data. A fair reading of sections 7 and 9 that gives meaning to both is that section 7 describes data sources relevant to assessing PCI case volumes and section 9 concerns the time frames to be used when data is acquired from those sources. Nothing in section 9 purports to regulate the scope of data sources Program by section 7. Consistent with this interpretation, the Program has incorporated data from other sources into its need calculation on prior occasions. For example, as described above, the Program incorporated Oregon inpatient data into its 2019 calculation of need, and incorporated both inpatient and outpatient data from Oregon hospitals on prior occasions. AR 243; see also AR 846-847 (the Program "used Oregon data in all prior versions of the methodology, including both inpatient data . . . and, when responses were provided, outpatient data from a survey taken by the Department of Oregon hospitals.").

The Final Order's erroneous interpretation of WAC 246-310-745(7) and (9) is the only basis offered to support the order's conclusion that the Program was justified in ignoring the data provided by Trios. The Final Order must be reversed on this ground because it is legally erroneous, is inconsistent with WAC 246-310-745, does not conform to the procedure required by that rule, and is arbitrary and capricious insofar as it abandons the Program's past practice of considering other sources when necessary to accurately forecast need. RCW 34.05.570(3)(b), (e), (h), (i).

VI. <u>CONCLUSION</u>

For the reasons set forth above, Trios respectfully requests that this Court reverse the Final Order's denial of Trios' application for a CN, remand for further proceedings, and order the Department to include the PCIs identified by Trios in its assessment of need on remand.

RESPECTFULLY SUBMITTED this 6th day of

February, 2023.

I certify that the foregoing memorandum contains 5,414 words, excluding words contained in the title sheet, tables of contents and authorities, certificate of service, signature blocks, any pictorial images or appendices, and this certificate.

OGDEN MURPHY WALLACE, PLLC

By /s/Madeleine C. Haller

Donald W. Black, WSBA #25272 E-Mail: dblack@omwlaw.com Paul J. Dayton, WSBA #12619 E-Mail: pdayton@omwlaw.com Madeleine C. Haller, WSBA #53341 E-Mail: mhaller@omwlaw.com Attorneys for RCCH Trios Health, LLC

CERTIFICATE OF SERVICE

On said day below I electronically served a true and accurate copy of the Appellant's Opening Brief, Division II, Cause No. 57403-9-II to the following parties:

Counsel for Respondent Washington State Department of Health

Jack E. Bucknell
Assistant Attorney General
Office of the Attorney General
Agriculture and Health Division
7141 Cleanwater Drive SW
PO Box 40109
Olympia, WA 98504-0109
Jack.bucknell@atg.wa.gov
AHDOlyEF@atg.wa.gov

Counsel for Respondent Kadlec Regional Medical Center

Brian Grimm
Perkins Coie LLP
1201 Third Avenue, Suite 4900
Seattle, WA 98101-3099
BGrimm@perkinscoie.com
SWyatt@perkinscoie.com

I declare under penalty of perjury under the laws of the State of Washington and the United States that the foregoing is true and correct.

Dated this 6th day of February, 2023 at Seattle, Washington

Bonnie Rakes

OGDEN MURPHY WALLACE PLLC

February 06, 2023 - 4:34 PM

Transmittal Information

Filed with Court: Court of Appeals Division II

Appellate Court Case Number: 57403-9

Appellate Court Case Title: RCCH Trios Health, LLC, Appellant v. Department of Health, et al., Respondents

Superior Court Case Number: 21-2-01992-1

The following documents have been uploaded:

574039_Briefs_20230206161932D2348530_1950.pdf

This File Contains: Briefs - Appellants

The Original File Name was 2761747.PDF

A copy of the uploaded files will be sent to:

- Jack.Bucknell@atg.wa.gov
- ahdolyef@atg.wa.gov
- bgrimm@perkinscoie.com
- brakes@omwlaw.com
- dblack@omwlaw.com
- mmoynan@scblaw.com
- pdayton@omwlaw.com

Comments:

Sender Name: Madeleine Haller - Email: mhaller@omwlaw.com

Address:

901 5TH AVE STE 3500 SEATTLE, WA, 98164-2059

Phone: 206-447-2232

Note: The Filing Id is 20230206161932D2348530